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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,655	11/28/2006	Matthew J. Scanlan	L0461.70156US00	5836

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WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,655	SCANLAN ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *180-206* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *180-200* is/are allowed.

6)☒ Claim(s) *201-206* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 11/19/08 in response to the Office Action of 6/19/08 are acknowledged and have been entered.

Claims 192-206 have been added by Applicant.

Claims 180-206 are pending.

Claims 180 and 189 have been amended by Applicant.

Claims 180-206 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections necessitated by amendments.

Objections Withdrawn

The objection to the specification is withdrawn.

Rejections Withdrawn

All previous rejections are withdrawn.

New Rejections Necessitated by Amendments

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 180-206 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 10, 11, 143, 162, 163, 191, 192, and 195 of copending Application No. 10/260,708. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3, 10, 11, 143, 162, 163, 191, 192, and 195 of copending Application No. 10/260,708 encompass species of instant claims 180-206.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 201-206 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumas et al (EP 1 033 401 A2; 9/6/00) in view of Altman et al (Science, 10/4/96, 274:94-96).

Claim 201 is drawn to a composition comprising an isolated polypeptide with a sequence as set forth as SEQ ID NO:55 or a fragment thereof that is at least 8 amino acids in length, a MHC molecule, and a pharmaceutically acceptable carrier, wherein the isolated polypeptide is complexed to the MHC molecule. Claim 202 is drawn to the isolated composition of claim 201, wherein the fragment is at least 9-100 amino acids in length. Claim 203 is drawn to a composition of claim 201 or 202 wherein the MHC molecule is a HLA class I molecule. Claim 204 is drawn to a composition of claim 201 or 202 wherein the MHC molecule is a HLA class I molecule. Claim 205 is drawn to a composition comprising (a) an isolated polypeptide with a sequence as set forth as SEQ ID NO:55 or a fragment thereof that is at least 8 amino acids in length, (b) an adjuvant, cytokine, or a costimulatory molecule, and (c) a pharmaceutically acceptable carrier.

Dumas et al teaches an isolated polypeptide, SEQ ID NO:4557, comprising a sequence set forth as a fragment of instant SEQ ID NO:55, wherein the fragment is at least 9 amino acids in length (see sequence comparison below). Dumas et al further teaches said polypeptide is to be evaluated for its effect on cytotoxic lymphocytes (paragraphs 296 and 300, in particular).

Dumas et al does not specifically teach a composition comprising said polypeptide complexed to a class I MHC costimulatory molecule and a pharmaceutical carrier. However, these deficiencies are made up in the teachings of Altman et al.

Altman et al teaches a method of evaluating effects of polypeptides on cytotoxic lymphocytes comprising exposing said lymphocytes to compositions comprising said polypeptides conjugated to MHC HLA class I costimulatory molecules and a pharmaceutical carrier (Figure 1, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to produce compositions comprising the polypeptide of Dumas et al conjugated to a MHC HLA class I costimulatory molecule and a pharmaceutical carrier in order to use said composition in the method of Altman et al to evaluate the effect of the polypeptide on cytotoxic lymphocytes because Dumas et al teaches said polypeptide is to be evaluated for its effect on cytotoxic lymphocytes (paragraphs 296 and 300, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing compositions comprising the polypeptide of Dumas et al conjugated to a MHC HLA class I costimulatory molecule and a pharmaceutical carrier because Dumas et al teaches said

polypeptide and Altman et al teaches a method comprising producing compositions comprising polypeptides conjugated to MHC HLA class I costimulatory molecules and a pharmaceutical carrier (page 94, in particular).. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Comparison of SEQ ID NO:4557 with instant SEQ ID NO:55:

```
Query Match             18.3%;  Score 247;  DB 3;  Length 51;
  Best Local Similarity   96.0%;  Pred. No. 7.1e-18;
  Matches   48;  Conservative    0;  Mismatches    2;  Indels    0;  Gaps
0;

Qy        184 MMQMFGLGAISLILVCLPIYCRSLFWRSEPADDLQRQDNRVVTGLKKQRR 233
              ||||  ||||||||||||||||||||||||||||||||||||||||||||
Db          1 MMQMXXLGAISLILVCLPIYCRSLFWRSEPADDLQRQDNRVVTGLKKQRR 50
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Allowable Subject Matter

Claims 180-200 are allowed.

Summary

Claims 201-206 are rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Examiner, Art Unit 1642